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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/509,787 | 05/23/2005 | Brian F. O'Dowd | 3477-110 | 3131 |
| 1059 | 7590 | 05/14/2007 | | |
| BERESKIN AND PARR 40 KING STREET WEST BOX 401 TORONTO, ON M5H 3Y2 CANADA | | | EXAMINER ULM, JOHN D | |
| | | | ART UNIT 1649 | PAPER NUMBER |
| | | | MAIL DATE 05/14/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/509,787

Applicant(s)

O'DOWD ET AL.

Examiner

John D. Ulm

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,8,11,16-20,27,30,31,34,37,38,41,43,46-49,56 and 59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,8,11,16-20,27,30,31,34,37,38,41,43,46-49,56 and 59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1) Claims 1, 2, 6, 8, 11, 16 to 20, 27, 30, 31, 34, 37, 38, 41, 43, 46 to 49, 56 and 59 are pending in the instant application. Claims 16, 8, 11, 16, 19, 20, 37, 41, 43 and 48 have been amended and claims 4, 5, 39, 40, 61, 62, 64 to 66, 68, 73 to 77, 84, 87, 90 to 93, 96, 97, 99 to 101, 103, 106, 112 to 115, and 122 have been canceled as requested by Applicant in the correspondence filed 28 February of 2007.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

4) Claims 37, 38, 41, 43, 46 to 49, 56 and 59 were withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 22 June of 2006. Because the elected and non-elected claims have all been amended to recite a method that employs a common distinguishing product, **those claims are hereby rejoined.**

Claim Rejections - 35 USC § 112

5) Claims 1, 2, 6, 8, 11, 16 to 20, 27, 30, 31, 34, 37, 38, 41, 43, 46 to 49, 56 and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for those reasons of record as applied to claims 1,2, 4 to 6, 8, 11, 17 to 20, 27, 30, 31 and 34 in section 7 of the office action mailed 30 November of

Art Unit: 1649

2006. These claims encompass subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As stated in the original rejection, it is clear from the express limitations of claim 8 that the instant claims are intended to encompass a method that employs a prokaryotic host cell. The summary of the invention on page 9 of the instant specification states that “[t]he inventors have shown that the incorporation of a nuclear localisation sequence (NLS) into a transmembrane protein (not containing an endogenous functional NLS) routes the protein from the cell surface into the nucleus of a cell in a time-dependent and ligand-independent manner”. The claimed method requires a difference between the distribution of transmembrane protein within a cell expressing upon exposure to a compound that interacts with that protein and the distribution of that protein in a cell that has not been exposed to that compound. One of ordinary skill in the art of receptor biology would have absolutely no reason to believe that the incorporation of an NLS into a transmembrane protein will have any effect at all on the localization of that protein in a prokaryotic cell upon exposure to a compound that interacts with that protein since a prokaryotic cell, by definition, has no nucleus.

Applicant has traversed this rejection on the premise that NLS motifs are recognized and bound by the importin α - β receptor complex, which is a cytosolic protein, and binding of this protein with the NLS results in transportation of the bound NLS-containing protein to the “nuclear core”. It is noted that the term “nuclear core” does not appear to be an art recognized term in the field of cell biology. As disclosed in

Art Unit: 1649

the instant specification, the transport mechanism upon which the instant invention is based serves to move proteins from the surface of a cell to the nucleus of a cell.

Because a prokaryotic cell lacks a nucleus, one of ordinary skill has no reasonable expectation that the components involved in the transport of a NLS into the nucleus of a eukaryotic cell would be present in a prokaryotic cell or functional therein if introduced exogenously. Applicant urges that a person skilled in the art would understand that the binding of a NLS motif by an importin α - β receptor complex **may** not be dependent on the presence of a nucleus in the cell and that the binding of a transmembrane protein comprising an NLS to this complex **may** be expected to alter the distribution of that protein from the membrane simply into the cytosol of the cell of a prokaryote. This is not found persuasive because there is absolutely no evidence of record that a prokaryotic cell processes a protein containing an NLS in any manner that distinguishes that protein from a protein lacking an NLS. Therefore, one of ordinary skill in the art of molecular biology has no reasonable expectation that the claimed invention would be operable in a prokaryotic cell.

In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that :

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other

Art Unit: 1649

embodiments can be made without difficulty **and their performance characteristics predicted by resort to known scientific law**; in cases involving unpredictable factors, such as most chemical reactions and **physiological activity**, scope of enablement varies inversely with degree of unpredictability of factors involved."

The instant claims are not enabled for the practice of the method recited therein in a prokaryotic cell because one of ordinary skill in the art of molecular biology can not predict, "by resort to known scientific law", that an NLS will be differentially processed by that cell as would be required for the operability of that method.

Response to Arguments

6) Applicant's arguments filed 28 February of 2008 have been fully considered but they are not persuasive.

Conclusion

7) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

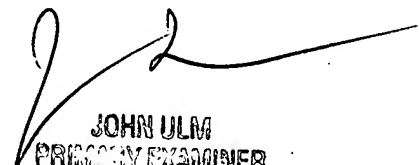
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1649

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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